1992.

Ministry of Agriculture, Fisheries and Food
Ergon House, c/o Nobel House, 17 Smith Square, London SW1P 3JR
Telephone: 071-238 3000 Direct line: 071-238
GTN: 238 Telex: 21271 Fax: ext. 6591 or

To all organisations on the attached list

25 September 1992

Dear Consultee

GENETIC MODIFICATION PROGRAMMES AND FOOD USE

Ministers have recently commissioned an ad hoc study of the ethical issues that may arise from the potential consumption of genetically modified organisms (GMOs) or their products and related issues. Details of the study group and their remit are given in the announcement at appendix A to this paper. It should be emphasised that the scope of the study does not extend to the ethics of genetic modification (GM) per se but is limited to the food use of organisms from GM programmes. Some basic information on genetic modification is provided in the enclosed fact sheets.

This study in part arises from a report by the Advisory Committee on Novel Foods and Processes (ACNFP) (see appendix B). The Committee had considered the safety of using as food, farm animals produced by GM research programmes aimed at the transfer of human genes to such animals in order to make possible the production of a range of pharmaceutical products. The resultant 'transgenic' animals would produce medically valuable, nature identical human blood proteins in their milk. However, the proposals considered by the ACNFP concerned only those animals in which the intended insertion of new genetic material had not occurred. The Committee concluded that for certain categories of animals produced by these programmes it was possible to determine unequivocally that the intended modification had not been achieved and that, therefore, the animals were perfectly normal and so raised no food safety concerns.

However, in framing their advice on safety the ACNFP also highlighted the possible ethical issues to arise from the marketing of animals from transgenic modification programmes as food. In commissioning this study Ministers have sought to obtain considered and informed advice on this and other related ethical issues which may arise, as outlined below.

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There appear to be four actual or potential types of development which could give rise to ethical concerns in relation to the consumption of food. These are summarised below:

- the transfer of human genes to food animals; (examples include the sheep in which a human blood clotting factor gene had been incorporated; both modified animals and those in which incorporation of the foreign DNA had not occurred could potentially be used for food);
- the transfer of genes from animals whose flesh is forbidden for food to certain religious groups to animals which they normally eat; (e.g pig for Muslims and Jews, or cattle for Hindus; in the United States, cattle have been modified to carry the porcine growth hormone);
- the introduction of animal genes into food crops which may be of particular concern to vegan vegetarians;
- the use, as animal feed, of organisms containing human genes; (eg yeast can be modified to produce human proteins of pharmaceutical value; consideration might be given to disposing of the spent yeast as animal feed).

At present none of the products referred to above is entering the human food or animal feed chains but it is the ethical concerns that could arise from such a practice that this study aims to address.

Initially the study team will attempt to assess likely future developments in this area and any information that you can provide on the nature of developments in the pipeline and their likely timescale would be very welcome. Additionally views are particularly invited on the ethical concerns that could arise from the type of developments described above and on the following points:

- whether there should be controls on the food use of any particular type of product and if so what form such controls should take and which products should be covered;
- whether concern might be met through labelling or other forms of information to consumers or by some other means.

The group would be most interested to have your views by 20 November. These should be sent to Mr Tim Davis, Study Group on Genetic Modification Programmes and Food Use, Ministry of Agriculture, Fisheries and Food, R425, Ergon House, c/o Nobel House, 17 Smith Square, London SW1P 3JR (FAX 071 238 6382).

In order to help inform debate on the issues raised by this consultation document, MAFF intends to make publicly available, at

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the end of the consultation period, copies of the responses received. The main Departmental Library at 3 Whitehall Place, London SW1 (tel 071 270 8419) will supply copies on request to personal callers or telephone inquirers who may produce further copies. It will be assumed, therefore, that your response can be made publicly available in this way, unless you indicate that you wish all or part of your response to be excluded from this arrangement.

If you have no objection to your response being made available for public examination in the way described above, would you please supply an additional copy of your response to this consultation document.

Yours sincerely

T J Davis

T J Davis
Secretary to the Study Group

CONSULTATION LIST - AD HOC STUDY

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BRITISH MEDICAL ASSOC (LONDON)
BRITISH MEAT MANUFACTURERS
BRITISH NUTRITION FOUNDATION
BRITISH RETAIL CONSORTIUM
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BRITISH STARCH INDUSTRIES ASSOC
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CARDINAL CAHAL DALY
CATHOLIC BISHOPS JOINT COMMITTEE ON BIOETHICAL ISSUES
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INTERNATIONAL SUPREME COUNCIL
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NATIONAL ASSOC OF WOMENS CLUBS
NATIONAL CITIZENS ADVICE BUREAUX COUNCIL
NATIONAL CONSUMER COUNCIL
NAT COUNCIL OF WOMEN OF GB
NATIONAL FARMERS UNION (LONDON)
NATIONAL FARMERS UNION (SWANSEA)

NATIONAL FARMERS UNION OF SCOTLAND
NATIONAL FED OF CONSUMER GROUPS
NAT FED OF MEAT TRADERS ASSOC
NATIONAL FED OF WOMENS INSTITUTES
NATIONAL FOOD ALLIANCE
NATIONAL HOUSEWIVES' ASSOC
NATIONAL UNION OF TOWNSWOMENS GUILDS
(NIAPA) N.I AGRICULTURAL PRODUCERS ASSOCIATION
(NIGTA) N.I GRAIN TRADE ASSOCIATION
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UK ACTION COMMITTEE FOR ISLAMIC AFFAIRS
UK FED OF BUSINESS & PROFESSIONAL WOMEN
UK FED OF HOME ECONOMISTS
ULSTER CURERS' ASSOCIATION
ULSTER FARMERS UNION
UNILEVER RESEARCH
UNION OF MUSLIM ORGANISATIONS OF UK AND EIRE

UNITED KINGDOM ISLAMIC MISSION (LONDON)
UNITED KINGDOM ISLAMIC MISSION (OLDHAM)
UNIVERSITY OF NOTTINGHAM (SCHOOL OF AGRICULTURE + FOOD SCIENCES)
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MAFF News Release
Ministry of Agriculture, Fisheries & Food, Whitehall Place, London SW1A 2HH. Press Office: 071-270 8973. Out of hours: 071-270 8080. Fax: 071-270 8443.

306/92 25 September 1992

MINISTER FORMS ETHICAL GROUP ON GENETICALLY MODIFIED FOODS

An independent expert group has been appointed by John Gummer, Minister of Agriculture, Fisheries and Food, to report on ethical concerns which might arise from the consumption of foods derived from genetic modification programmes and associated issues.

Replying to a Parliamentary Question from David Tredinnick MP (Bosworth), who asked the Minister how he intends to respond to ethical concerns over the use of genetically modified organisms as food Mr Gummer said:

"I have asked the Reverend John Polkinghorne, President of Queens' College Cambridge, to chair a study into this and various related issues. The other members of the group will be Professor Derek Burke, Vice Chancellor of the University of East Anglia, Professor Brian Heap, Director of Research at the AFRC Institute of Animal Physiology and Genetic Research, Mrs Harriet Kimbell, Vice-Chairman of the Consumers' Association, Mr Richard Callaghan, Controller of ASDA's Technical Division and the Reverend Arthur Peacocke, Warden-Emeritus of the Society of Ordained Scientists.

"The study's terms of reference will be:

- to consider future trends in the production of transgenic organisms; to consider the moral and ethical concerns (other than those relating to food safety) that may arise from the use of food products derived from production programmes involving such organisms; and to make recommendations.

"Recently we have seen significant developments towards the use of genetic modification in food production. This technology has the potential to benefit farmers, food producers and consumers by extending the range, quality and types of food available. However, the Government is also aware that these developments may, in some instances, raise ethical and moral concerns for some consumers.

"Therefore we thought it right to give early consideration to these issues. The new advisory group will consider likely future trends in the use of genetic modification in food production and concerns which might arise from the consumption of food from such programmes, and recommend how those concerns might be addressed.

"I believe the issues with which the Committee are concerned need to be widely debated and I know the study team will be inviting views from all interested groups and individuals. I have asked the study team to report to me within a year."

Biographical Notes

Chairman

Reverend Professor J C Polkinghorne MA, PhD, ScD, FRS
President of Queens' College, Cambridge. Formerly Professor of Mathematical Physics at Cambridge University, before taking Holy Orders. A member of the Advisory Committee on Novel Foods and Processes.

Members

Professor D C Burke BSc, PhD, HonLLD, DL
Vice-Chancellor of University of East Anglia. Chairman of the Advisory Committee on Novel Foods and Processes and a member of the Advisory Committee on Genetic Modification.

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Mr R Callaghan BSc MSc
Controller of Technical Division of ASDA. An Associate of the Institute of Food, Science and Technology and a former member of the Food From Britain Quality Council.

Professor R B Heap PhD, ScD, FRS
Director of Research at the AFRC Institute of Animal Physiology and Genetics Research, and Director of Science at the Agricultural and Food Research Council.

Mrs H Kimbell
Solicitor and lecturer at the College of Law. Vice-Chairman of the Consumers' Association and member of the Consumer Panel.

Reverend Dr A R Peacocke, DSc, ScD, DD, SOSc,
Warden-Emeritus of the Society of Ordained Scientists. Honorary Chaplain of Christ Church Cathedral, Oxford.

Note for Editors

1. It is expected that the study group will issue a consultation document shortly which will invite the views of a wide range of interested parties. The Group has been asked to report to the Minister of Agriculture in 12 months time.

2. The Group is being established in part to follow up a recommendation from the Advisory Committee on Novel Foods and Processes (ACNFP). The Committee was asked to advise on the acceptability as food of animals used in genetic modification programmes. In providing advice on the food safety issues the ACNFP suggested that the ethical acceptability of such animals also needed to be considered.

END

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FACTSHEET

NUMBER 1

WHAT IS GENETIC MODIFICATION?

Every organism has its own "blueprint" in its genes. "**Genetic modification**" means making changes to those genes and the way they are combined together.

In its broadest sense, genetic modification has always happened in nature and natural changes are necessary for evolution. They are also the basis of selective breeding of animals and plants, which has been done for centuries. Recent scientific advances have allowed us to achieve genetic modification by removing or inserting particular genes. This type of **genetic modification** is often called gene splicing or genetic engineering and is the subject of this note.

Genes - Our Inheritance

Everyone is familiar with the idea of **genetic inheritance**, that offspring will resemble their parents to a high degree but are not identical to either one. We expect acorns to grow into oak trees and cows to give birth to calves; we know that children's hair and eye colours are inherited from their parents. Appearance is largely inherited from parents because the genes that offspring inherit control, ultimately, each characteristic.

The basic principles of genetic inheritance are true for all kinds of organisms, whether people, animals, plants or microbes. The genes controlling every organism's form are found in its **chromosomes**; the chromosomes themselves are in every cell that makes up the organism's body. The chromosomes of larger organisms (and many smaller ones such as yeast and algae) are found in each cell's nucleus. People have 46 chromosomes in every cell in their bodies while fruit flies have 4 and bread-making wheat has 42 in every cell.

Bacteria are single celled organisms. They do not have a nucleus but they do have a single circular chromosome in each cell. All chromosomes perform the same function: they contain their organism's genes like beads on a string. All chromosomes have the same basic structure: a very long **DNA** * molecule supported by special proteins.

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* DNA stands for deoxyribonucleic acid - the chemical name of genetics' double helix. It has two strands joined together a bit like the two halves of a double-ended zipper and twisted lengthwise. Each 'tooth' of the zipper is a separate chemical sub-unit. Viruses, which are very much smaller than even the smallest bacteria, have their genes on just one or two strands (occasionally more) of DNA or of the closely related chemical RNA: ribonucleic acid.

Chromosomes

The sequence of chemical sub-units in a DNA molecule forms a coded message which defines which building blocks (called amino acids) are used, and their sequence, to make up the various proteins which the organism makes in order to develop, grow and multiply. This organisation of information can be likened to a library: each part of the code being like individual letters which are arranged into words and sentences to form a book (**the gene**); the books are arranged in stacks of shelves (**the chromosome**); and the whole library of books compares to the organism's complete set of chromosomes. Scientists are now able to read more and more of the books in the libraries of different organisms' genes.

Each cell in a complex organism contains the entire library of its genes. This has to be copied whenever a cell grows and divides. Sexual reproduction (except in bacteria) creates a new library as each parent donates half of its own library to its offspring. Offspring receive two copies of each gene, one from each parent, rather like two different editions of the same book. Sometimes the maternal copy predominates and sometimes the paternal one does. These processes of copying and making libraries are reliable but not quite perfect; mistakes occur and thus sports or mutations arise naturally.

Sources of Variation

People have been using naturally occurring variation for thousands of years. Domesticated animals and cultivated crops have been produced as a result. In the Middle Ages, for example, shire horses were selectively bred for their size and power. We now also have many breeds of dog designed to suit different requirements. Yet these developments were only achieved by painstakingly selecting the right breeding stock and watching and waiting for each useful variation to turn up.

Breeders of farm animals still have to rely on selecting from the variation naturally available in the stock when they wish to develop new breeds. But for crops and microorganisms, techniques have been developed over the last 50 years or so which can increase the chance of a change in their DNA occurring. Indeed, the most popular British barley in the 1970s, "Golden Promise", was developed in this way. But these techniques still allow progress to be made only when the chance occurrence of a useful mutation comes up. A breeder may need to grow and assess thousands of cross-bred organisms before a really useful one is found.

Intentional Changes

Now our science has developed to the stage where, in many cases, we can identify the gene (ie the book in the library) that codes for a particular desired characteristic - colour pattern in a garden flower, leanness in a farm animal or pest resistance in a crop for example. We can then extract the gene we want and insert it into the plant, microbe or animal we wish to develop. And the two organisms involved, the one donating the gene we want and the one into which we insert it, do not have to be able to breed with each other.

The techniques involved are complex in practice but involve four basic steps. First, the DNA from a cell of the organism donating the gene is broken down and the pieces separated. Second, the gene is located. Third, the gene is copied many times. Finally, the copies are introduced into the organism which we wish to develop. It is these steps (greatly simplified in this description) that have collectively come to be known as **"genetic modification"**.

Other MAFF GMO Factsheets:

No 2 What Controls will there be on Genetic Modification to ensure Safety?

No 3 Why is Genetic Modification Important?

For further information, contact:

Steve Gilson
Biotechnology Unit
MAFF
Room 314b
Whitehall Place West
London SW1A 2HH

Tel No: 071 270 8090

MAFF Food Safety Directorate

foodsense

FACTSHEET

NUMBER 2

WHAT CONTROLS WILL THERE BE ON GENETIC MODIFICATION TO ENSURE SAFETY?

The first of these factsheets describes in simple terms what genetic modification is and the third describes why it is important. This note describes the controls that will be placed on the use of genetic modification in order to safeguard human health and the environment.

In the UK, there are already **controls on genetic modification** which the Government is at this moment strengthening. Further legislative controls, especially regarding food, have been widely discussed. In addition, the Government already operates a non-statutory scheme to clear foods which come from genetically modified sources. These controls are all described briefly in this note.

Existing Legislation

Just because someone invents a new technology it does not mean that the products of that technology escape any controls. **Existing legal requirements** will automatically apply to them. Thus, for example, a veterinary medicine produced in a new way still has to be approved under the Medicines Act and an animal which has some genetically modified genes in it is protected by all the animal welfare requirements that are already in place to protect animals that have been bred conventionally.

Existing British controls on genetic modification in respect of human health and safety are contained within the general duties of the Health and Safety at Work etc Act 1974 and in the **Genetic Manipulation Regulations 1989** (SI No 1810) made under the Act. The Regulations, which replaced the Health and Safety (Genetic Manipulation) Regulations 1978, are operated by the Health and Safety Executive (HSE); similar regulations operate in Northern Ireland. The 1989 Regulations require anyone who intends to carry out any activity involving genetic modification to notify the HSE in advance and to carry out a detailed assessment of the risks that the proposed activity would involve. The only exception to the requirement to notify the HSE in advance is for certain lower risk activities where a simplified and retrospective notification is required instead.

Proposed Legislation

Although the existing regulations have worked well, the Government is preparing **new controls** which will extend and replace them in 1992 and (revised) draft Regulations were issued for comment in August. Copies of the Consultation Paper can be obtained from:

Department of the Environment
Room A347
43 Marsham Street
London SW1P 3PY (tel: 071 276 8353)

The proposed regulations, to be made later this year (1992), will build on the system of risk assessment and notification already operating in this country. Broadly speaking, they will require everyone who intends to carry out any act in which organisms are genetically modified, or intends to culture, store, use, market, release etc genetically modified organisms (GMOs), to carry out (and keep records of) **risk assessments** beforehand. In addition they will have to **notify** the Department of the Environment or the Health and Safety Executive of their proposals and, for certain activities, they will also have to obtain a **written consent**; consents will be required for all proposed releases to the environment and all proposals to sell products consisting of or containing GMOs. These requirements will be underpinned by general duties to prevent environmental damage which will complement existing general duties to protect human health and safety. These regulations will implement the environmental, and human health and safety requirements of two European Community Directives agreed in 1990 which include a Community-wide clearance system for the marketing of products consisting of or containing GMOs.

At the moment the Government's scheme to clear foods which come from GMOs operates on a voluntary basis but this is expected to change. The Government has powers under the 1990 **Food Safety Act** to introduce statutory controls on novel processes and foods (including those from GMO sources). However, the European Commission recently published its proposal for a Council Regulation on novel foods and novel food ingredients, which include foods consisting of or containing GMOs. Further information can be obtained from:

Ministry of Agriculture, Fisheries and Food
Chemical Safety of Food, Branch A
Room 429d
Ergon House
17 Smith Square
London SW1P 3JR (tel: 071 238 6380)

● Advice available to Government

The Government exercises the powers it has, and will have, to control GMOs in the light of the advice it receives from a number of specialist **independent committees**. Between them, these committees' responsibilities cover the full range of technical questions that a proposal, for example to sell a food made from a GMO, might raise. Where a proposal raises issues which concern the expertise of more than one committee, then we ensure that each one considers the proposal and the advice of all is taken into account.

For example, if someone in this country proposed genetically modifying potatoes to improve their taste or nutritional value, they would have to notify the HSE and provide a risk assessment (see paragraph 4). In considering such a notification, the HSE would consult:

> the Advisory Committee on Genetic Modification (ACGM)
> (which is serviced by HSE). ACGM advises the Health and Safety Commission, the HSE and the Government on aspects of work activities including genetic modification.

When the plant breeders wished to start growing the new potatoes in field plots to see how well they did, they would first need to submit a further risk assessment (and in future would need to obtain a specific consent - see paragraph 6). This application would be considered by:

> the Advisory Committee on Releases to the Environment (ACRE) (serviced by DOE and HSE).
> ACRE advises the Health and Safety Commission, the HSE and the Government on all aspects of human and environmental health and safety of the introduction into the British environment of GMOs.

If the development were successful, the plant breeders would (amongst other requirements) be well advised to submit their proposals to:

> the Advisory Committee on Novel Foods and Processes (ACNFP)
> (which is serviced by the Department of Health (DH) and the Ministry of Agriculture, Fisheries and Food (MAFF)).

In future the Government expects this to become a mandatory requirement (see paragraph 7). The ACNFP, in considering such an application, may itself seek the views of further advisory committees before reaching a conclusion on whether the novel food derived from a genetically modified source would be acceptable. In particular, the views of:

the Food Advisory Committee (FAC) (serviced by MAFF) which is responsible for advising on the labelling, composition and chemical safety of food, including food additives, flavourings, processing aids and contaminants;

the Committee on Toxicity of Chemicals in Food Consumer Products and the Environment (COT) (serviced by DH) which provides expert advice on matters of toxicology. The ACNFP may similarly seek expert advice from two parallel DH committees on Carcinogenicity (COC) and Mutagenicity (COM); and

the Committee on Medical Aspects of Food Policy (COMA) (serviced by DH).
COMA and its Panel advise, amongst other things, on nutritional questions.

Conclusion

The Government aims to ensure that, in particular, crops and foods produced by GMOs will be as safe as those from more conventional systems. Therefore, genetic modification techniques are already controlled and new rules covering the experimental release of GMOs and their sale will soon be introduced. We already operate a voluntary clearance system for foods from GMOs (or which contain GMOs) and we are working with the EC Commission to develop statutory EC-wide legal controls on such foods.

Other MAFF GMO Factsheets:

No 1 What is Genetic Modification?

No 3 Why is Genetic Modification Important?

For Further Information, contact:

Steve Gilson
Biotechnology Unit
MAFF
Room 314b
Whitehall Place West
London SW1A 2HH

Tel No. 071 270 8090

MAFF Food Safety Directorate

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FACTSHEET

NUMBER 3

WHY IS GENETIC MODIFICATION IMPORTANT?

Genetic modification (also called genetic engineering) is widely predicted to be of great importance for economic development in the next few years. Indeed, in time its impact on our daily lives could be as significant as the development of steam power in the eighteenth century, or of transistors and microchips in our lifetime. This note gives some examples of the implications that these developments might have for the agriculture and food industries.

How could genetic modification help the agriculture and food industries? Progress in researching and developing applications of genetic modification for the agriculture and food industries (amongst others) is taking place in many countries. We can already see that it can be used to improve ways of diagnosing and treating diseases of crops and farm animals, to protect plants and farm animals from diseases and pests and to improve the quality of our food. Other industries can also benefit.

Benefits for Farming

Let us look first at **disease diagnosis.** Although it may be plain to the stockman and his vet that a particular cow in the herd is not well, her symptoms may indicate several possible diseases which require different treatments. The vet is faced either with taking a sample, having it analysed in a laboratory and waiting days for the result or with starting treatment at once even though it is not quite clear what the best course is.

Genetic modification offers new ways of greatly increasing the sensitivity, specificity and speed of tests so that vets can carry a diagnostic kit around with them. For example, genetically modified microbes or cells may be used to produce reagents for rapid immunological tests. So, in future, problems that take days or weeks to identify can be analysed literally within minutes. This is obviously better for the animals as well as the farmer. Genetic modification will also be used increasingly to make new vaccines and medicines to treat animals.

The arable farmer can benefit from similar developments. In some of the common crop diseases, the crop continues to look healthy for some while

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TAKEN OUT OF TH[illegible]

after it has been infected. By the time the effects of the disease appear, it may have done significant harm. This means that farmers often spray against these diseases as a precaution and so may be applying pesticides when there is no disease in their crops. By using diagnostic kits farmers could tell whether their crops were infected and spray only when the disease was present.

Genetic modification can enable plant breeders to develop **new crops** much more rapidly and with more certainty that their new variety will do what they want. Conventional plant breeding is slow and uncertain. Using two distantly related varieties as parents in order to combine their best characteristics, for example yield in one case and drought tolerance in the other, and then selecting their offspring for a number of generations is laborious and can take many years to achieve some degree of success. But, if genes responsible for drought tolerance can be identified, it might be possible to snip them out of that variety and splice them into the high yielding one, significantly speeding up the development of a new, useful variety of the crop.

Genetic modification makes it possible to transfer genes between plants that do not usually breed with one another. This could help breeders make useful changes to crop plants which are difficult to make at the moment: increased levels of nutrients such as vitamins, better taste and texture, improved keeping quality and higher resistance to pests and diseases are examples.

Benefits for Consumers

Consumers could benefit from these developments. There should be a greater variety of foods to choose from, perhaps with improved nutritional qualities. In addition, the advantages which genetic modification may bring to the grower and processor, such as improved pest resistance or keeping quality, could be passed on to the consumer.

Many consumers would like tastier tomatoes that did not bruise so easily. Genetic modification of existing varieties may be able to provide them. Some of the best tasting potatoes are highly susceptible to diseases which less flavoursome varieties are able to resist. Again, genetic modification may provide a solution.

In ways such as this we may also be able further to reduce the need to use pesticides on our crops without risking poor harvests which can result from pest or disease attacks. The countryside generally could thus benefit from the use of some genetically modified crops.

Other Possibilities

Although we think of farming in the United Kingdom as being essentially concerned with food production, some crops are already grown for other purposes - for example, linseed whose oil is used in the paint and plastics industries. Genetic modification of oilseed rape may provide a range of oils for manufacturing industries that is less expensive than that used currently. The genetic modification of certain seeds could provide raw materials for the pharmaceutical industry.

Economic progress or development depends on **innovation**, on finding new and better ways to do tasks, or to make things; and on creating new services and goods that people never knew they would use until they were available. Televisions and fax machines are examples of such goods. If our examples of possible uses of genetic modification seem unconnected, it is because the range of new possibilities opened up by this technology is so broad.

Other MAFF GMO Factsheets:

No. 1 What is Genetic Modification?

No. 2 What Controls will there be on Genetic Modification to ensure Safety?

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ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

THE USE OF ANIMALS FROM TRANSGENIC BREEDING PROGRAMMES AS FOOD

Introduction

1. Increasing interest is being shown in the genetic modification of farm animals to produce medically valuable human proteins. In most cases the human gene involved is linked to the animals' milk protein genes so that the required protein is secreted in the milk thus simplifying extraction. We have been asked to advise on the acceptability as food of animals used in genetic modification programmes to produce such pharmaceutical products. In this paper we review the techniques employed to produce transgenic animals, the potential outcome of such programmes and the safety and other issues raised. We make a number of general recommendations.

Techniques employed to produce transgenic animals

2. The technique currently used for genetically modifying farm animals is to microinject DNA coding for the human protein into cells taken from a fertilised egg prior to cell differentiation. The cells are subsequently implanted into a surrogate mother where they develop in the usual way. Potentially 4 classes of animals result from such modification experiments:-

- in a small percentage (with current technology usually about 0.1%) of the animals produced in this way the gene for the desired human protein is present and is expressed so that ultimately the protein is secreted by the lactating animal. (The group is referred to as class I animals in this paper).

- some animals will also develop (around 1%) which, although they contain the foreign gene, do not express it (class II animals);

- there is a small possibility of creating "mosaics"; that is animals containing multiple genetically different populations of cells in some of which the human gene is absent (class III animals);

- in the majority of animals the human gene will be totally absent (class IV animals);

3. The small number of animals which are found to contain human genes are termed 'transgenic' and are used as founder animals to establish a transgenic line using traditional methods of breeding with (usually) non-transgenic partners. Since only half the genetic information from each partner is transmitted to their offspring, half these (on average) completely lack the human gene (these "negative" animals are termed class V animals).

4. The Committee has recently been asked to consider whether those animals in which the human gene is not incorporated (essentially classes III to V above) might be used as human food. The Committee has not been asked to consider the use, as food, of products from animals in which a foreign gene is present (ie class I or II animals), whether or not it is expressed, and is not aware of any proposals to do so. Nevertheless since this is an issue which may have to be addressed at some stage this paper considers the issues raised by all classes of animals.

Present position regarding transgenic animals

5. At present guidelines issued by the Advisory Committee on Genetic Manipulation recommend that transgenic animals or their products should not be released for human or animal food without the prior agreement of the ACNFP. To date modification experiments to produce transgenic animals have been on a relatively small scale and we understand the carcasses of all animals involved are incinerated. However, as more such transgenics are produced and the scale of production of human protein grows the commercial loss incurred by discarding all the animals from a transgenic production programme is likely to increase markedly.

Identification of animals in each class

6. The first issue we addressed was whether individual animals can be identified unequivocally as belonging to one of the five classes defined above. The Committee concluded that with currently available immunologic techniques it would be possible to detect the presence of human proteins in animals and their products. The Committee further noted that techniques

based on the polymerase chain reaction (PCR) would, with appropriate experimental controls, be able to detect the presence of a single copy of a particular gene in a cell of an analytical sample. Application of these techniques to sample cells taken from first generation animals raised from cells which had been microinjected with foreign DNA would indicate if the foreign protein and gene were present and hence could identify animals in classes I and II.

7. However, the Committee noted that a particular problem arose in relation to the possible creation of 'mosaics'. There is a small though finite possibility that micro-injection of cells from fertilised eggs might give rise to first generation animal mosaics in which the gene, might be present only in particular cells or organs. These mosaics could easily be missed during screening for the human gene. Thus first generation animals raised from cells which have been subjected to micro-injection with human DNA could not be viewed with certainty as 'negative' for the human gene even if an analytical sample showed its absence. However, if a first generation animal mosaic is crossed with a non-transgenic animal, the human gene would only be inherited if the gene were present in the reproductive tissues. But in such a case any foreign DNA in the mosaic parent would be inherited according to Mendelian genetics. That is, if inherited it would be present throughout the cells of the second generation; if not it would be completely absent from the second generation progeny.

8. In short the combination of immunological and PCR techniques could be used to identify first generation animals in classes I and II. Because of the possibility of mosaics the status of apparently negative first generation animals would be uncertain. But if these animals were subsequently crossed with non-transgenic partners, second generation negative animals could be viewed as true negatives as could any class V type animals produced in any post-modification breeding programme. In principle therefore it is possible to distinguish with certainty those animals which carry the human gene, from those that do not, provided an extra generation is bred to rule out the possibility of complication by mosaicism. It seems, however, that at present the costs of demonstrating an animal is truly negative might outweigh its value as food.

Safety concerns

9. The second issue we considered was whether animals produced in a transgenic programme are safe to use as human or animal feed. It follows from paragraph 8 above that, since it can be demonstrated unequivocally that certain animals have not been modified it is possible to conclude that they give rise to no special safety concern. There would need to be detailed consideration on a case-by-case basis of the safety for food use of any animals shown to be transgenic.

Ethical concerns

10. The third issue we considered related to possible ethical concerns. The Committee noted that it would be breaking new ground if it were to recommend that, because the unmodified animals described above could be regarded as safe they were acceptable for use in human food. It recognised the strong feeling of some consumers about the genetic modification of animals and that concerns could be raised by the potential use of even unmodified animals from transgenic breeding programmes as food. The Committee considered that this issue needs to be addressed by Government before a decision on the use of any animals from transgenic breeding programmes is taken.

Possible labelling issues

11. The unmodified animals described above are not covered by the interim advice which the Food Advisory Committee has given concerning the labelling of foods from genetically modified organisms. The Committee recommends that if these animals are cleared for use in food, the Food Advisory Committee should be invited to consider whether special labelling should be required.

Conclusions

12. The Committee concludes that:

- second generation animals in which the absence of foreign genetic material can be demonstrated unequivocally by PCR analysis are unmodified and could be cleared for food use on safety grounds;

- the safety of transgenic animals for food use would have to be considered on a case by case basis;

- because first generation animals may be mosaics it is not possible to conclude on the basis of PCR analysis that they are unmodified; they should thus be governed by the same arrangements that are applied to known transgenics.

- the broader ethical issues arising from the food use of animals which are derived from genetic modification programmes involving genes coding for human proteins whether or not they themselves have been modified need to be addressed by Government;

- the Food Advisory Committee should be invited to consider the labelling of unmodified animals if their use for food is approved.